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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,566	01/07/2005	Douglas J. MacNeil	21141YP	5273

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EXAMINER	
WEDDINGTON, KEVIN E	

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1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,566	MACNEIL ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-73* is/are pending in the application.

4a) Of the above claim(s) *61-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-60 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3-24-05; 12-11-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 56-73 are presented for examination.

Applicants' preliminary amendment and drawings filed January 7, 2005; and the information disclosure statements filed March 24, 2005 and December 11, 2006 have been received and entered.

Applicants' election filed December 11, 2006 in response to the restriction requirement filed November 7, 2006 has been received and entered. The applicants elected the invention described in claims 56-60 and 73 (Group I) with elected species for NPY5 antagonist, 3-oxo-N-(5-phenyl-2-pyrazinyl)-spiro[isobenzofuran-1(3H),4'-piperidine]-1'carboxamide, and for the NPY1 antagonist, J-115814 with traverse.

Applicants' traverse is not deemed persuasive for reasons set forth in the previous Office action dated November 7, 2006; therefore, the restriction requirement is hereby made Final.

Claims 61-72 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 56-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 8-11 of U.S. Patent No. 5,908,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application teaches a composition comprising a NPY5 antagonist of formula I and an anti-obesity agent such as a NPY1 antagonist, and the patented application teaches a composition comprising a metabolic rate modifying agent and a feeding behavior modifying agent. Note in the patented application, the metabolic rate modifying agent can be a NPY1 antagonist and the feeding behavior modifying agent can be a NPY5 antagonist. Note the two components of the patented application's composition are the same as the present application's composition. However, the patented application's components are broad and the present application's components are specific; therefore, the patented application encompasses the present application.

Claims 56-60 are not allowed.

Claim 56 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/429,721. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the present

claims and the copending claims lies in that in the copending claims, an additional agent is administered with the presently claimed active agents.

The copending claims would anticipate the present claims because the present claims recite "comprising" and thus open the claims to the inclusion of additional active agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 56 is not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56, 57 and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection.

Claims 56, 57 and 73 described compounds that are NPY1 antagonists. The instant claims cover all compounds having the pharmaceutical property of being a NPY1 antagonist to treat obesity. Describing a compound by its functions will not

substitute for written description of the structure of the compound. The invention should be described in such a way as to described what the invention is, not what the invention does. Describing the function of a compound fails to distinguish the compound from other molecules or agents that can perform the same functions.

Undue experimentation is a conclusion reaches by weighing the noted factual considerations set forth below as seen in In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1401 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

Claims 56, 57 and 73 are directed to compounds that are NPY1 antagonists that are used to treat obesity. The instant claims cover all compounds having pharmaceutical property of being known as a compound (NPY1 antagonist) to treat obesity. Although claim 57 lists specific examples of compounds which are alleged to have the property to treat obesity, and claims 56 and 73 are directed to a variety of compounds with the functional description of being known as a compound which is alleged to have the property to treat obesity.

The instant claims are very broad. For instance, claims 56 and 73 are to a plethora of compounds of as described by the functional properties as being known to treat obesity.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

One skilled in the art would not predict from the instant disclosure which compounds would fall under the umbrella of functional description of being known as broadly as a NPY1 antagonist. In fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding predictable results, chemical and biological compounds often react unpredictably under different circumstances.

The breadth of the claims

The claims are very broad and inclusive to all NPY1 that are used to treat obesity.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the combination of a NPY5 antagonist derived from formula I combined with a NPY1 antagonist such as nalmefene or sibutramine only.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the skilled artisan would be able to extrapolate from the disclosure and examples provided to make and possibly use the claimed invention. The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. (In re Fischer, 427 F. 2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823).

The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether "undue experimentation" is required to make and use the instant invention. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if

it is merely routine, or of the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all the compounds or agents that are broadly known to possess the property of treating obesity as described in this specification. In view of the information set forth supra, the instant disclosure is not seen to be sufficient to describe the use of any compound , which is regarded as the functional description of a compound (NPY1 antagonist) for treating obesity.

Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 56, 57 and 73 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56-60 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukami et al. (6,326,375 B1) of PTO-1449 in view of Kanatani et al., "A Typical Y1 Receptor Regulates Feeding Behaviors: Effects of a Potent and Selective Y1 Antagonist, J-115814", Molecular Pharmacology, Vol. 59, No. 3, pp. 501-505 (2001) and further in view of De Lacharriere et al. (5,858,024).

Fukami et al. teach spiro compounds derived from the same formula I as set forth in applicants' claim 56. Note the compounds are used to treat metabolic diseases such as obesity (see column 3, line 64). Note particular to column 15, lines 21-22 discloses applicants' preferred spiro compound, 3-oxo-N-(5-phenyl-2-pyrazinyl)-spiro[isobenzofuran-1(3H),4'-piperidine]-1'carboxamide.

The instant invention differs from the cited reference in that the cited reference does not teach the addition of a second agent, a NPY1 antagonist such as J-115814. However, the secondary reference, Kanatani et al., teaches J-115814 as an agent used to suppress the feeding appetites of obese mice (see the abstract). Note on page 505, last paragraph states J-115814 produce the reduction of spontaneous food intake thus possessing ant-obesity activity.

Clearly, one skilled in the art would have assumed the combination of two individual agents well-known to treat obesity into a single composition would give an additive effect in the absence of evidence to the contrary.

The instant invention differs from the cited references in that the cited references do not teach the instant composition can be placed into a kit. However, the tertiary reference, De Lacharriere et al., teaches the first and second compositions are packages separately in the form of a kit, in an arrangement which is well-known to those skilled in the art, in particular in the pharmaceutical field (see column 2, lines 6-10.

Clearly, one skilled in the art would have been highly motivated to place the two individual agents in a kit since placing compounds into a kit is well-known and old in the art.

Claims 56-60 and 73 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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June 5, 2007